510(k) Summary (21 CFR § 807.92(c))

NOV 7 2012

Submitter:	Walk Vascular, LLC 17171 Daimler Street Irvine, CA 92614
Contact:	Angela B. Soito, Esq. Regulatory Consultant to Walk Vascular LLC Telephone: 650.303.0525 Email: soitoconsulting@gmail.com
Date Summary Prepared:	04 October 2012
Device Trade Name:	ClearLumen Thrombectomy System
Common Name:	Embolectomy / Thrombectomy Catheter
Classification Name:	Embolectomy Catheter (21 CFR §870.5150)
Product Code:	DXE
Equivalent Devices:	Kerberos Rinspirator (K050130) Possis AngioJet (K972610) Medtronic Export AP Aspiration Catheter (K081573) eV3 X-Sizer Catheter System (K021096)

Device Description:
The ClearLumen Thrombectomy Device consists of a thrombectomy catheter, saline drive unit ("SDU") and waste collection bottles. The thrombectomy catheter is a multi-lumen 6F or 7F guide compatible, 135 cm in length and is used over the wire. The catheters have a 7 cm rapid exchange length. The device is intended for use with conventional 0.014" guidewires. The proximal end of the catheter contains a polycarbonate hub that connects to the SDU and provides access to the infusion and aspiration lumens. The distal end of the catheter shaft is comprised of an atraumatic tip. The ClearLumen Catheter is connected to the battery operated SDU which allows for simultaneous lysing and aspiration of thrombus from the treatment site. The SDU contains a port for connection to a standard saline bag. The device uses a toggle switch to turn the pump on and off.

Intended Use:
The ClearLumen Thrombectomy System is intended to break-up, remove/aspirate soft emboli and thrombus from the peripheral vasculature.

Non-Clinical Performance Data:
Design verification testing confirmed that the ClearLumen device performs according to the stated intended use. Device evaluation consisted of functional testing performed pursuant to Walk Vascular's

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Walk Vascular LLC
c/o Angela B. Soito, Esq.
ABS Consulting Services, LLC
17171 Daimler St.
Irvine, CA 92614 US

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Re: K120508
Trade/Device Name: ClearLumen Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: October 11, 2012
Received: October 15, 2012

Dear Ms. Soito:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number if Known: TBD K120508

Device Name: ClearLumen Thrombectomy Device

Indications for Use:

The ClearLumen Thrombectomy System is intended to break-up, remove/aspirate soft emboli and thrombus from the peripheral vasculature.

Prescription Use ☒ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120508